UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

26/JUL/2011

MEMORANDUM

Subject:	Name of Pesticide Product:	DECCO 400 EC
	EPA File Symbol:	2792-TT
	DP Barcode:	D387217
	Decision No.:	444654
	Action Code:	R310
	PC Code:	018301 (chlorpropham)

From: Eugenia McAndrew, Biologist
Technical Review Branch
Registration Division (7505P)

E McAndrew
B Hanson

To: Rosemary Kearns, RM Team 22
Fungicide Branch
Registration Division (7505P)

Applicant: DECCO US Post-Harvest Inc.
1713 S. California Avenue
Monrovia, CA 91016

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Chlorpropham	40.0
Other Ingredient(s):	60.0
Total:	100.0%

ACTION REQUESTED: RM requests: "Registrant has submitted new application for growth regulator containing the active ingredient Chlorpropham."

BACKGROUND: DECCO US Post-Harvest Inc. has submitted a six pack of acute toxicity studies to support the registration of the proposed product, DECCO 400 EC, EPA File Symbol 2792-TT. The studies were conducted at Eurofins/Product Safety Laboratories, Inc. with assigned MRID numbers 483721-02 to -07. A basic CSF and dated January 28, 2011, a label and company letter are included in the submission. An Agency contractor, Summitec Corporation, conducted the primary review of the studies. TRB performed the secondary review and made changes as necessary.

RECOMMENDATIONS: The six studies have been reviewed and are classified as acceptable.

The acute toxicity profile for DECCO 400 EC, EPA File Symbol 2792-TT, is as follows:

Acute oral toxicity	IV	Acceptable	MRID 48372102
Acute dermal toxicity	IV	Acceptable	MRID 48372103
Acute inhalation toxicity	IV	Acceptable	MRID 48372104
Primary eye irritation	IV	Acceptable	MRID 48372105
Primary skin irritation	IV	Acceptable	MRID 48372106
Dermal sensitization	Sensitizer	Acceptable	MRID 48372107

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for the proposed product as obtained from the Label Review System:

PRODUCT ID #: 002792-00077

PRODUCT NAME: DECCO 400 EC

PRECAUTIONARY STATEMENTS

SIGNAL WORD: (optional) CAUTION

Hazards to Humans and Domestic Animals:

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

First Aid: No statements are required. Category III statements may be used.

Wear: Long-sleeved shirt and long pants, socks, shoes, and chemical resistant gloves.

DATA EVALUATION RECORD

CHLORPROPHAM
[DECCO CIPC EC 400]

STUDY TYPE: ACUTE ORAL TOXICITY - RAT [OPPTS 870.1100; OECD 425]
ACUTE DERMAL TOXICITY - RAT [OPPTS 870.1200; OECD 402]
ACUTE INHALATION TOXICITY - RAT [OPPTS 870.1300; OECD 403]
ACUTE EYE IRRITATION - RABBIT [OPPTS 870.2400; OECD 405]
ACUTE DERMAL IRRITATION - RABBIT [OPPTS 870.2500; OECD 404]
DERMAL SENSITIZATION - GUINEA PIG [OPPTS 870.2600; OECD 406]
MRID: 48372102, 48372103, 48372104, 48372105, 48372106, and 48372107

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
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Task Order No. 3-B-17

Primary Reviewer:
Donna L. Fefee, D.V.M.

Signature: Donna Fefee
Date: 6-22-2011

Secondary Reviewers:
Thomas C. Marshall, Ph.D., D.A.B.T.

Signature: Thomas C. Marshall
Date: JUN 23 2011

Robert H. Ross, M.S., Program Manager

Signature: Robert H. Ross
Date: JUN 23 2011

Quality Assurance:
Jennifer Goldberg, B.S.

Signature: Jennifer Goldberg
Date: JUN 23 2011

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Reviewer: Eugenia McAndrew **Date:** July 26, 2011
Risk Manager (EPA): 22

STUDY TYPE: Acute Oral Toxicity - Rat; OPPTS 870.1100; OECD 425

TEST MATERIAL: DECCO CIPC EC 400; 40% Chlorpropham; Lot No.: "Formula: PB 06-1H0;" EPSL Reference No. 100624-15H; Light yellow clear liquid; specific gravity 1.033 g/mL; pH: 7.5 (at 22° C., as a 1:39 w/w solution in water); expiration date: June 22, 2014; stored at room temperature; expected to be stable for the duration of testing.

CITATION: Durando, J. (2010) DECCO CIPC EC 400: acute oral toxicity up and down procedure in rats. Study Number 30211. Unpublished study prepared by Eurofins PSL, Dayton, New Jersey. October 26, 2010. MRID 48372102.

SPONSOR: DECCO US Post-Harvest Inc., 1713 South California Avenue, Monrovia, California.

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 48372102), three fasted, female, Sprague-Dawley-derived albino rats were given a single oral gavage dose of undiluted DECCO CIPC EC 400 (40% Chlorpropham; Lot No.: "Formula: PB 06-1H0") at a dose level of 5000 mg/kg bw (limit test). The animals were treated on day 0 and observed for up to 14 days. The animals were 10-11 weeks old, weighed 190-232 g, and were supplied by Ace Animals, Inc., Boyertown, Pennsylvania.

Abnormal clinical signs were limited to hypoactivity, irregular respiration, piloerection, and hunched or prone posture, which were exhibited by all animals on day 0 after dosing, and decreased fecal volume from one animal on day 1. There were no deaths or abnormal gross necropsy findings, and all of the animals gained weight during both weeks of the study.

Oral LD_{50} Females > 5000 mg/kg bw

Based on the acute oral LD_{50} in females, DECCO CIPC EC 400 is in EPA Toxicity Category IV.

This acute oral study is classified as Acceptable. It satisfies the guideline requirement for an acute oral study (OPPTS 870.1100; OECD 425) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION: Individual animals were dosed as follows:

Animal No.	Dose level (mg/kg)	Short-Term Outcome	Long-Term Outcome
3101	5000	S	S
3102		S	S
3103		S	S

S = survival D = death

Initially, a single animal was dosed at 5000 mg/kg; due to the absence of mortality, two additional animals were dosed at 5000 mg/kg bw, simultaneously.

Statistics: There was no mention of statistical analysis in the study report. The dose progression selections, stopping criteria determinations and/or LD_{50} and confidence limit calculations were consistent with AOT425statpgm, i.e. Acute Oral Toxicity (Guideline 425) Statistical Program (Westat, version 1.0, May 2001). Statistical evaluation of results is not required under OPPTS 870.1100.

A. Mortality: There were no deaths.

B. Clinical observations: All animals exhibited hypoactivity, irregular respiration, piloerection, and hunched or prone posture on day 0 after dosing, and one animal had decreased fecal volume on day 1. No abnormal clinical signs were observed during the remainder of the study interval, and all three animals gained weight during both weeks of the study.

C. Gross Necropsy: There were no abnormal findings.

D. Reviewer's Conclusions: In agreement with the study author, the acute oral LD_{50} for females is greater than 5000 mg/kg bw. This places the test material in EPA Toxicity Category IV.

E. Deficiencies: None.

Reviewer: Eugenia McAndrew **Date:** July 26, 2011
Risk Manager (EPA): 22

STUDY TYPE: Acute Dermal Toxicity - Rat; OPPTS 870.1200; OECD 402

TEST MATERIAL: DECCO CIPC EC 400; 40% Chlorpropham; Lot No.: "Formula: PB 06-1H0;" EPSL Reference No. 100624-15H; Light yellow clear liquid; specific gravity 1.033 g/mL; pH: 7.5 (at 22° C., as a 1:39 w/w solution in water); expiration date: June 22, 2014; stored at room temperature; expected to be stable for the duration of testing.

CITATION: Durando, J. (2010) DECCO CIPC EC 400: acute dermal toxicity study in rats – limit test. Study Number 30212. Unpublished study prepared by Eurofins PSL, Dayton, New Jersey. October 26, 2010. MRID 48372103.

SPONSOR: DECCO US Post-Harvest Inc., 1713 South California Avenue, Monrovia, California.

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 48372103), a group of five male and five female Sprague-Dawley-derived albino rats was dermally exposed to undiluted DECCO CIPC EC 400 (40% Chlorpropham; Lot No.: "Formula: PB 06-1H0") at a dose of 5000 mg/kg bw for 24 hours. The doses were applied to clipped application sites on the dorsal trunk, measuring approximately 2 inches by 3 inches (~10% of the body surface area), using a 4-ply gauze pad secured with 3-inch Durapore tape wrapped around the trunk. The day of application was considered to be day 0, and the animals were observed for 14 days. The animals were 8-9 weeks old (males: 252-259 g, females: 188-204 g) and supplied by Ace Animals, Inc., Boyertown, Pennsylvania.

There were no deaths, abnormal systemic clinical signs, or abnormal gross necropsy findings, and all of the animals gained weight during both weeks of the study. All males had adhesive residue around the dose site on days 1-4 or 1-5, and all females had mechanical damage around the dose site (attributed to unwrapping) on days 1-4 or on day 1, only.

LD_{50} Males > 5000 mg/kg bw
LD_{50} Females > 5000 mg/kg bw
LD_{50} Combined > 5000 mg/kg bw

Based on the acute dermal LD_{50} for males, females, and the combined sexes, DECCO CIPC EC 400 is in EPA Toxicity Category IV.

This acute dermal study is classified Acceptable. It does satisfy the guideline requirement for an acute dermal study (OPPTS 870.1200; OECD 402) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Dose (mg/kg bw)	Mortality/Number Tested		
	Males	Females	Combined
5000	0/5	0/5	0/10

Statistics: There was no mention of statistical analysis in the study report. Statistical evaluation of results is not required under OPPTS 870.1200.

A. Mortality: There were no deaths.

B. Clinical observations: There were no abnormal systemic clinical signs, and all of the animals gained weight during both weeks of the study. Adhesive residue was observed around the dose sites of all males on days 1-4 or 1-5, and, on day 1 or days 1-4, all females had mechanical damage around the dose site attributed to unwrapping.

C. Gross Necropsy: There were no abnormal findings.

D. Reviewer's Conclusions: In agreement with the study author, the acute dermal LD_{50} for males, females, and the combined sexes is greater than 5000 mg/kg bw. This places the test material in EPA Toxicity Category IV.

E. Deficiencies: None.

Reviewer: Eugenia McAndrew **Date:** July 26, 2011
Risk Manager (EPA): 22

STUDY TYPE: Acute Inhalation Toxicity - Rat; OPPTS 870.1300; OECD 403

TEST MATERIAL: DECCO CIPC EC 400; 40% Chlorpropham; Lot No.: "Formula: PB 06-1H0;" EPSL Reference No. 100624-15H; Light yellow clear liquid; pH: 7.5 (at 22° C., as a 1:39 w/w solution in water); expiration date: June 22, 2014; stored at room temperature; expected to be stable for the duration of testing.

CITATION: Durando, J. (2010) DECCO CIPC EC 400: acute inhalation toxicity study in rats. Study Number 30213. Unpublished study prepared by Eurofins PSL, Dayton, New Jersey. October 26, 2010. MRID 48372104.

SPONSOR: DECCO US Post-Harvest Inc., 1713 South California Avenue, Monrovia, California.

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 48372104), a group of five male and five female Sprague-Dawley-derived rats was exposed by nose-only inhalation for 4 hours to aerosolized DECCO CIPC EC 400 (40% Chlorpropham; Lot No.: "Formula: PB 06-1H0") at a mean gravimetric concentration of 2.05 mg/L, with mean MMAD of 2.15 microns and GSD of 1.76. Exposure was on day 0, and the animals were observed for 14 days. The animals were 9-10 weeks old (males: 308-352 g; females: 216-250 g) and supplied by Ace Animals, Inc., Boyertown, Pennsylvania.

There were no deaths or abnormal clinical signs, and all of the animals gained weight during both weeks of the study. Abnormal gross necropsy findings were limited to mottled discoloration of the kidneys in three males and one female.

LC_{50} Males > 2.05 mg/L
LC_{50} Females > 2.05 mg/L
LC_{50} Combined > 2.05 mg/L

Based on the four-hour inhalation exposure LC_{50} for males, females, and the combined sexes, DECCO CIPC EC 400 is in EPA Toxicity Category IV.

This acute inhalation study is classified as acceptable. It does satisfy the guideline requirement for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Nominal Conc. (mg/L)	Mean Gravimetric Conc. (mg/L)	MMAD µm	GSD	Mortality/Number Tested		
				Males	Females	Combined
10.32	2.05	2.1-2.2	1.73-1.78	0/5	0/5	0/10

Test Atmosphere / Chamber Description: The exposure atmosphere was generated by using a peristaltic pump to meter the test material to a 1/4-inch JCO atomizer supplied with filtered compressed air at 30 psi and approximately 23.4 L/minute. Additional compressed air was introduced into the chamber at approximately 2.3 L/minute, in order to create a vortex at the chamber inlet to more uniformly distribute the test atmosphere. The nose-only inhalation chamber (Mini-Nose Only Inhalation Chamber, ADG Developments, Ltd.) had an internal volume of approximately 6.7 L.

Gravimetric Conc. (mg/L)	2.05±0.08 (range: 1.93-2.13)
Chamber Volume (L)	6.7
Mean Total Airflow (L/min)	25.7
Temperature (° C)	21-23
Relative Humidity (%)	59-68
Time to T_{99} equilibrium (minutes)	1.2

Test atmosphere concentration: Gravimetric samples were collected from the breathing zone of the animals at six intervals during exposure, using a vacuum pump and pre-weighed glass fiber filters. Collections were carried out for 3 minutes at airflows of 4 L/min. The mass collected was then divided by the total volume of air sampled.

Particle size determination: Two samples withdrawn from the breathing zone of the animals were analyzed using an eight-stage Andersen cascade impactor to determine the particle size distribution of the test atmosphere. The mass median aerodynamic diameter (MMAD) and geometric standard deviation (GSD) were determined graphically, using two-cycle logarithmic probit axes, and are given above.

A. Mortality: There were no deaths.

B. Clinical observations: No abnormal clinical signs were noted upon removal from the exposure tubes or during the remainder of the study interval. All animals gained weight during both weeks of the study.

C. Gross Necropsy: Mottled discoloration of the kidneys was noted in three males and one female.

D. Reviewer's Conclusions: The four-hour exposure LC_{50} for males, females, and the combined sexes is greater than 2.05 mg/L. Based on these results, the test material is classified as EPA Toxicity Category IV.

E. Deficiencies: None.

Reviewer: Eugenia McAndrew **Date:** July 26, 2011
Risk Manager (EPA): 22

STUDY TYPE: Primary Eye Irritation - Rabbit; OPPTS 870.2400; OECD 405

TEST MATERIAL: DECCO CIPC EC 400; 40% Chlorpropham; Lot No.: "Formula: PB 06-1H0;" EPSL Reference No. 100624-15H; Light yellow clear liquid; pH: 7.5 (at 22° C., as a 1:39 w/w solution in water); expiration date: June 22, 2014; stored at room temperature; expected to be stable for the duration of testing.

CITATION: Durando, J. (2010) DECCO CIPC EC 400: primary eye irritation study in rabbits. Study Number 30214. Unpublished study prepared by Eurofins PSL, Dayton, New Jersey. October 26, 2010. MRID 48372105.

SPONSOR: DECCO US Post-Harvest Inc., 1713 South California Avenue, Monrovia, California.

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 48372105), 0.1 mL of undiluted DECCO CIPC EC 400 (40% Chlorpropham; Lot No.: "Formula: PB 06-1H0") was instilled into the conjunctival sac of the anesthetized right eye of three young adult, female, New Zealand albino rabbits, and the upper and lower lids were held shut for approximately one second. Prior to instillation, 2-3 drops of ocular anesthetic (Tetracaine Hydrochloride Ophthalmic Solution, 0.5%) were placed into both the treated and control eye of each animal. Eyes were scored for ocular irritation according to the Draize method 1, 24, 48, and 72 hours after instillation, and fluorescein staining was done at 24 hours and as needed thereafter. The anesthetized but otherwise untreated left eye of each animal served as a control. The animals were supplied by Robinson Services Inc., Clemmons, North Carolina; the body weights and exact ages of the animals were not provided.

One hour after instillation of the test material, all treated eyes exhibited conjunctival redness (grade 1) and discharge (grade 2). Two treated eyes were clear at 24 hours, and the third had grade 1 conjunctival redness at 24 hours and was clear at 48 hours. There were no observations of corneal opacity or iritis, and no abnormal systemic clinical signs were recorded. The maximum mean total score (MMTS) was 6.0, recorded 1 hour after test material instillation.

In this study, the formulation is minimally irritating. DECCO CIPC EC 400 is classified as EPA Toxicity Category IV for primary eye irritation.

This study is classified as Acceptable. It does satisfy the guideline requirement for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Observations	Number "positive"/number tested			
	Hours			
	1	24	48	72
Corneal Opacity	0/3	0/3	0/3	0/3
Iritis	0/3	0/3	0/3	0/3
Conjunctivae:				
Redness*	0/3	0/3	0/3	0/3
Chemosis*	0/3	0/3	0/3	0/3
Discharge**	3/3	0/3	0/3	0/3
Severity of Irritation: Mean Total Score	6.0	0.7	0.0	0.0

* Score of 2 or more required to be considered "positive."

** Not considered a positive irritation effect; however, scores of 2 or greater are noted here for completeness.

A. Observations: There were no observations of corneal opacity or iritis. One hour after instillation of the test material, all treated eyes exhibited conjunctival redness (grade 1) and discharge (grade 2). Two treated eyes were clear at 24 hours, and the third had grade 1 conjunctival redness at 24 hours and was clear at 48 hours. No abnormal systemic clinical signs were recorded.

B. Results: The maximum mean total score (MMTS) was 6.0, recorded 1 hour after test material instillation.

C. Reviewer's conclusions: In agreement with the study author, the test material is minimally irritating to the eye and is classified as EPA Toxicity Category IV for primary eye irritation.

D. Deficiencies: As a minor deficiency, the ages of the animals were not provided.

Reviewer: Eugenia McAndrew **Date:** July 26, 2011
Risk Manager (EPA): 22

STUDY TYPE: Primary Dermal Irritation - Rabbit; OPPTS 870.2500; OECD 404

TEST MATERIAL: DECCO CIPC EC 400; 40% Chlorpropham; Lot No.: "Formula: PB 06-1H0;" EPSL Reference No. 100624-15H; Light yellow clear liquid; pH: 7.5 (at 22° C., as a 1:39 w/w solution in water); expiration date: June 22, 2014; stored at room temperature; expected to be stable for the duration of testing.

CITATION: Durando, J. (2010) DECCO CIPC EC 400: primary skin irritation study in rabbits. Study Number 30215. Unpublished study prepared by Eurofins PSL, Dayton, New Jersey. October 26, 2010. MRID 48372106.

SPONSOR: DECCO US Post-Harvest Inc., 1713 South California Avenue, Monrovia, California.

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 48372106), three young adult, female, New Zealand albino rabbits were dermally exposed to 0.5 mL of undiluted DECCO CIPC EC 400 (40% Chlorpropham; Lot No.: "Formula: PB 06-1H0") for 4 hours. The doses were applied to intact, clipped, 6-cm^2 application sites on the trunk, and covered by a 4-ply gauze pad secured with semi-occlusive 3-inch Micropore tape wrapped around the trunk. The animals were observed at 30-60 minutes and 24, 48, and 72 hours and at 7, and 10 days after patch removal, and any irritation at the dose sites was scored according to Draize. The animals were supplied by Robinson Services Inc., Clemmons, North Carolina; the body weights and exact ages of the animals were not provided.

At 30-60 minutes after patch removal, all treated sites exhibited well-defined erythema (score=2) and very slight edema (score=1). At 24 hours, two sites still had well-defined erythema with very slight edema, and the third site had very slight erythema (score=1) without edema. At 48 and 72 hours, one site had well-defined erythema with very slight edema, and two sites had very slight erythema without edema. At 7 days, one site had very slight erythema without edema, while the other two sites were clear, and all sites were clear of irritation at 10 days post-treatment. No abnormal systemic clinical signs were reported.

In this study, DECCO CIPC EC 400 is classified as EPA Toxicity Category IV for primary dermal irritation. The Primary Irritation Index (PII) = 2.17.

This study is classified as Acceptable. It does satisfy the guideline requirement for a primary skin irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

INDIVIDUAL SKIN IRRITATION SCORES [Erythema/Edema]

Animal No.	Sex	Hours				Days	
		0.5 - 1	24	48	72	7	10
3501	F	2/1	2/1	1/0	1/0	0/0	0/0
3502	F	2/1	1/0	1/0	1/0	0/0	0/0
3503	F	2/1	2/1	2/1	2/1	1/0	0/0
Severity of Irritation - Mean Score		2.0/1.0	1.7/0.7	1.3/0.3	1.3/0.3	0.3/0	0/0

A. Observations: At 30-60 minutes after patch removal, all treated sites exhibited well-defined erythema (score=2) and very slight edema (score=1). At 24 hours, two sites still had well-defined erythema with very slight edema, and the third site had very slight erythema (score=1) without edema. At 48 and 72 hours, one site had well-defined erythema with very slight edema, and two sites had very slight erythema without edema. At 7 days, one site had very slight erythema without edema, while the other two sites were clear, and all sites were clear of irritation at 10 days after patch removal. No abnormal systemic clinical signs were reported.

B. Results: The PDII is 2.17.

C. Reviewer's Conclusions: Based on the slight irritation at 72 hours, the test material is classified as EPA Toxicity Category IV.

D. Deficiencies: As a minor deficiency, the ages of the animals were not provided.

Reviewer: Eugenia McAndrew **Date:** July 26, 2011
Risk Manager (EPA): 22

STUDY TYPE: Dermal Sensitization – Guinea Pig; OPPTS 870.2600; OECD 406

TEST MATERIAL: DECCO CIPC EC 400; 40% Chlorpropham; Lot No.: "Formula: PB 06-1H0;" EPSL Reference No. 100624-15H; Light yellow clear liquid; pH: 7.5 (at 22° C., as a 1:39 w/w solution in water); expiration date: June 22, 2014; stored at room temperature; expected to be stable for the duration of testing.

CITATION: Durando, J. (2010) DECCO CIPC EC 400: dermal sensitization study in guinea pigs (Buehler method). Study Number 30216. Unpublished study prepared by Eurofins PSL, Dayton, New Jersey. October 26, 2010. MRID 48372107.

SPONSOR: DECCO US Post-Harvest Inc., 1713 South California Avenue, Monrovia, California.

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 48372107), twenty young adult, male, Hartley albino guinea pigs were tested with undiluted DECCO CIPC EC 400 (40% Chlorpropham; Lot No.: "Formula: PB 06-1H0") using the Buehler method. A separate naïve control group of ten males was treated during challenge only. The animals were supplied by Elm Hill Breeding Labs, Chelmsford, Massachusetts and weighed 350-476 g; exact ages of the animals were not reported.

Following challenge with a 75% w/w mixture of test material in mineral oil, positive dermal reactions were observed on a total of 7/20 treated animals at 24 hours, and persisted through 48 hours on 4 of these animals. No positive dermal reactions were noted on naïve controls following challenge. No abnormal systemic clinical signs were reported, and all of the animals gained weight over the course of the study.

Based on this study, DECCO CIPC EC 400 *is* a dermal sensitizer.

This study is classified as acceptable. It does satisfy the guideline requirement for a primary dermal sensitization study (OPPTS 870.2600; OECD 406) in the Guinea pig.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. PROCEDURE

A. Induction: The dorsal area and flanks of the animals were clipped one day prior to each treatment. For each of three successive weekly inductions, 0.4 mL of the undiluted test material was applied to the left side of each animal using an occlusive 25 mm Hill Top Chamber® and secured in place with adhesive tape wrappings for six hours. Reactions were scored 24 and 48 hours post application.

B. Challenge: Twenty-seven days after the first induction, the test animals were challenged with 0.4 mL of a 75% w/w mixture of test material in mineral oil (the highest non-irritating concentration according to preliminary testing), applied to naive sites on the right side of each animal for 6 hours using the same procedure. Reactions were scored 24 and 48 hours post application.

C. Naive Controls: At challenge, a separate "naive" group of ten previously untreated animals was also treated with 0.4 mL of a 75% w/w mixture of test material in mineral oil. Reactions were scored 24 and 48 hours post application.

II. RESULTS and DISCUSSION:

A. Reactions and duration: Following the first induction, very faint erythema (score=0.5) was noted on 10 and 2 application sites at 24 and 48 hours, respectively. Following the second induction, very faint erythema was noted on 10 and 4 application sites at 24 and 48 hours, respectively, and faint, usually confluent, erythema (score=1) was noted on 1 application site at 24 hours only. Following the third induction, very faint erythema was noted on 15 and 6 application sites at 24 and 48 hours, respectively, and faint, usually confluent, erythema was noted on 1 application site at 24 hours only. Following challenge, moderate erythema (score=2) was noted on 1/20 application sites (of treated animals) at both 24 and 48 hours, and faint, usually confluent, erythema was noted on 6/20 and 3/20 application sites at 24 and 48 hours, respectively, giving a total of 7/20 animals with "positive" reactions, four of which persisted through 48 hours. Very faint erythema was noted on 10/20 and 8/20 treated animals at 24 and 48 hours, respectively, and was also noted on 5/10 and 2/10 naïve controls at these same respective times.

B. Positive control: The study report included the results from a positive control study with alpha-Hexylcinnamaldehyde (EPSL Study #28478, completed on December 30, 2009). This positive control study was not conducted within six months of the in-life dates of the submitted study (July 12-August 11, 2010). However, the reviewer also had access to the results from a different positive control study conducted at this same laboratory with alpha-Hexylcinnamaldehyde within the proper time frame (EPSL Study #30298, completed on August 19, 2010 and summarized in MRID 48444508 [EPSL Study #30798]). The induction and challenge procedures used in both main dermal sensitization studies were similar. The methods used in EPSL #30798 were stated to be similar to these, and the results of the study were appropriate.

C. <u>Reviewer's Conclusions</u>: In agreement with the study author, the test material *is* a dermal sensitizer.

ACUTE TOX ONE-LINERS:

1. DP BARCODE: 387217				
2. PC CODE: 018301				
3. CURRENT DATE: July 26, 2011				
4. TEST MATERIAL: DECCO CIPC EC 400 [Chlorpropham]				
Study/Species/Lab Study # /Date	**MRID**	**Results**	**Tox. Cat.**	**Core Grade**
Acute oral toxicity / rat Eurofins PSL Study #30211 / October 26, 2010	48372102	Oral LD_{50} Females > 5000 mg/kg	IV	A
Acute dermal toxicity / rat Eurofins PSL Study #30212 / October 26, 2010	48372103	LD_{50} Males > 5000 mg/kg LD_{50} Females: > 5000 mg/kg LD_{50} Combined > 5000 mg/kg	IV	A
Acute inhalation toxicity / rat Eurofins PSL Study #30213 / October 26, 2010	48372104	LC_{50} Males >2.05 mg/L LC_{50} Females >2.05 mg/L LC_{50} Combined >2.05 mg/L	IV	A
Primary eye irritation / rabbit Eurofins PSL Study #30214 / October 26, 2010	48372105	Minimally irritating; MMTS=6.0, at 1 hour	IV	A
Primary dermal irritation /rabbit Eurofins PSL Study #30215 / October 26, 2010	48372106	Slight irritation at 72 hours	IV	A
Dermal Sensitization /guinea pig Eurofins PSL Study #30216 / October 26, 2010	48372107	*Is* a sensitizer	--	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, W = Waived